

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ROBERT L. GARBER, ET AL.,

Plaintiffs,

v.

PHARMACIA CORPORATION, ET AL.,

Defendants.

Civil Action No. 3:03-cv-1519(AET)

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**AMICUS BRIEF OF THE JAMA AUTHORS IN SUPPORT OF DEFENDANTS'
MOTION FOR A PROTECTIVE ORDER PREVENTING THE DISCLOSURE
OF CERTAIN PERSONAL FINANCIAL INFORMATION OF THE JAMA AUTHORS**

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Amici Fred E. Silverstein, M.D., Gerald A. Faich, M.D., M.P.H., Jay L. Goldstein, M.D., Lee S. Simon, M.D., Theodore P. Pincus, M.D., Andrew Whelton, M.D., Robert Makuch, Ph.D., Glenn Eisen, M.D., Naurang M. Agrawal, M.D., and William F. Stenson, M.D. respectfully submit this letter brief pursuant to the Court's July 13, 2005 Order granting them leave to appear as *amici curiae* in support of defendants' request for a protective order limiting the production required under Plaintiffs' Fourth Notice to Produce Documents (the "Fourth Request"), and in opposition to plaintiffs' motion to compel the production of certain financial information relating to *amici*.

Amici also request leave to participate in oral argument in support of defendants' motion for a protective order and in opposition to plaintiffs' motion to compel production.¹

INTEREST OF AMICI

Amici are independent professionals who, in various capacities, participated in a study conducted from 1998 through 2000 to assess the gastrointestinal safety of the drug known as celecoxib, which was and is marketed under the name Celebrex®. That study was known as the Celecoxib Long-Term Arthritis Safety Study (the "CLASS Study"). *Amici* also co-authored an article entitled "Gastrointestinal Toxicity With Celecoxib vs. Nonsteroidal Anti-Inflammatory

¹ Should the Court grant this request, a *pro hac vice* motion will be filed for the counsel who will argue on behalf of *amici*.

Drugs for Osteoarthritis and Rheumatoid Arthritis [.] The CLASS Study: A Randomized Controlled Trial,” which was published in the *Journal of the American Medical Association* in September 2000 (the “JAMA Article”).

During the conduct of the CLASS Study, the defendants compensated *amici* for their consulting services. In addition, both before and since the CLASS Study, a number of *amici* have participated in other research and consulting projects that were unrelated to the conduct of the CLASS Study and the publication of the JAMA Article.

THE PROCEDURAL POSTURE

Plaintiffs’ counsel served a subpoena *duces tecum* on each of the *amici* seeking “documents sufficient to ascertain all money you have received from Searle, Pharmacia or Pfizer, and the reasons therefor.” *Amici* objected to the subpoenas on grounds that they were overly broad, unduly burdensome and sought irrelevant information, the production of which would chill scientific research. Plaintiffs then served their Fourth Request upon defendants, seeking information identical to that previously requested from *amici*. The only difference is that the documents are now being sought from the entity that paid the money (defendants) rather than the individuals who received the money (*amici*).

Defendants have objected to the production of the requested documents in deference to the privacy rights of *amici* (*see* Defendants’ Letter Brief dated May

27, 2005 and Defendants' Reply Letter Brief dated June 13, 2005). Counsel for *amici* and the parties have conferred on several occasions concerning the production of the requested information. Counsel for *amici* proposed a compromise to plaintiffs' counsel and stated that they would not object to defendants' production of documents reflecting monies paid for services in connection with the conduct of the CLASS Study and publication of the JAMA Article. Plaintiffs, however, would not agree to any limitation other than limiting the time period of their request to two years prior to the publication of the JAMA Article.

Plaintiffs have argued that the documents in question are relevant to their claims. Yet, as we show below, whatever relevance the requested documents may have in this litigation is outweighed by the harm that disclosure would inflict on *amici's* privacy interests and, more broadly, by the chilling effect that would be created if independent professionals knew that their participation in safety studies of new drugs could lead to disclosure not just of personal financial information related to the study in which they participated, but of their entire financial history and dealings with the sponsor of the study.

ARGUMENT

A. The Court Should Balance *Amici's* Privacy Rights Against the Plaintiffs' Interest in the Requested Information

When discovery demands clash with privacy interests, courts should balance the requesting party's need for the disputed information against the rights of the resisting individuals. Plaintiffs, however, have made no effort to balance the relevant considerations. Rather, plaintiffs take the position that because they deem the information to be relevant to bias, they are entitled to it. That is not the approach courts have taken.

In Choate v. State Farm Lloyds, 2005 U.S. Dist. LEXIS 8123 (N.D. Tex. May 5, 2005), the court discussed the importance of an individual's privacy rights in deciding motions for protective orders under Fed. R. Civ. P. 26(c). The Choate court found that it could, "in appropriate circumstances, limit or prohibit the discovery of materials, in order to protect a person's privacy interests. When a party objects that its opponent's discovery requests invade a person's privacy interests, the Court's role is to balance the person's legitimate claims of privacy against the need of the opponent for the discovery." Id. at *9 (internal quotations omitted). Likewise, in Cockrum v. Johnson, 917 F. Supp. 479 (E.D. Tex. 1996), the court in a habeas corpus action denied the state's request to examine personal letters written by a criminal defendant -- despite the letters' clear relevance to the case -- in order to protect the letter writer's right to privacy. The court

acknowledged that the “right to privacy encompasses . . . an individual[’s] interest in avoiding the disclosure of personal matters[,]” and went on to say that “[r]ather than requiring discovery without regard for a party’s privacy interests, the proper course is to balance a party’s legitimate claims of privacy against the need of the opponent for the discovery.” *Id.* at 481-82.

**B. In Light of Their Status as Non-Party Medical Researchers,
Amici’s Financial Information Merits Protection in this Litigation**

Both Choate and Cockrum involved information sought from parties to the litigation. Unlike the parties in those cases, *amici* have not voluntarily injected themselves into this litigation. Unlike defendants, they are not corporate entities whose financial dealings are subject to close public scrutiny. Nor are they salaried employees of the defendants. Rather, *amici* are independent professionals of national and international renown in their various fields who lent their medical and scientific expertise to the development of new pharmaceuticals.

Settled case law makes clear that, as independent medical researchers, *amici’s* privacy claims are due particular deference. In Federation of Physicians and Dentists, 63 F.Supp.2d 475 (D. Del. 1999), the district court protected non-party physicians’ personal financial records from discovery despite the government’s claims that the records were crucial to a price-fixing investigation. The court found that the relevance of the information did not outweigh the doctors’

privacy interests, particularly because the doctors were not parties to the litigation. The court explained that “[f]inancial information of non-parties in a lawsuit has been held by courts to be private *and not routinely available for discovery*. The right of privacy and the right to keep confidential one's financial affairs are well-recognized when the information involves non-parties, even though they may be allied to the parties.” Federation of Physicians and Dentists, 63 F.Supp.2d at 479 (internal quotation omitted) (emphasis added).

The Third Circuit also has recognized the need for courts to balance the relevance of discovery requests against the privacy interests of non-party physicians. In DeMasi v. Weiss, 669 F. 2d 114 (3d Cir. 1982), the Court found that a district court’s order directing non-party physicians to reveal their gross incomes threatened powerful privacy interests: “[i]t can scarcely be denied that the public exposure of one’s wallet or purse is, in the abstract, an invasion of privacy. Nor can it be denied that private individuals have legitimate expectations of privacy regarding the precise amounts of their incomes.” DeMasi, 669 F.2d at 119.

In an effort to minimize the intrusive nature of their document requests, plaintiffs argue that they seek only “summary documents” from defendants reflecting the total amount of compensation paid to *amici*. Plaintiffs’ argument is unpersuasive for at least two reasons. First, nowhere in their motion to compel production of the requested documents do plaintiffs indicate that they seek only

“summary” information. Indeed, plaintiffs’ motion to compel makes clear that plaintiffs seek “[a]ll documents concerning any monies, compensation, remuneration, payments or items of any kind” paid to *amici*. Plaintiffs’ Motion to Compel Production of Documents (“Mot. to Compel”) at 1 (May 2, 2005) (emphasis added). See also Plaintiffs’ Opposition to Motion to Intervene (“Mot. to Intervene Opp.”) at 8 (June 6, 2005) (“[p]laintiffs’ Requests to defendants seek all documents concerning payments, offers of payment, or promises of future payments” to *amici*) (emphasis added). While, as part of the meet-and-confer process, plaintiffs offered to narrow the scope of their demands, they also made clear that any such narrowing was without prejudice to “their right to seek more detailed documents sought by the document request, in the future, if necessary.” Mot. to Compel at 4. Thus, any suggestion that plaintiffs are seeking only “summary” documents is completely illusory.²

Second, even if plaintiffs sought only information deemed to be “summary,” that universe of documents nevertheless significantly implicates *amici*’s privacy rights. While plaintiffs contend that “summary documents” are “not ‘personal financial information,’” Mot. to Intervene Opp. at 4, the Third Circuit’s decision in DeMasi, 669 F.2d 114, clearly holds otherwise. In DeMasi, non-party physicians

² Equally illusory is exactly what plaintiffs consider to be “summary documents.” Nowhere have they offered any definition of the term and, given plaintiffs’ aggressive approach to this litigation, their definition of “summary” documents surely is broad enough to implicate *amici*’s privacy rights.

objected to a district court's order in civil litigation requiring that they provide "a written statement under oath of [their] gross income" *Id.* at 116 n.3. The Third Circuit found the disclosure of even that summary financial information to "constitute an immediate, irreparable violation of [the non-parties'] right of privacy." *Id.* at 122. In reaching that conclusion, the Third Circuit relied heavily on the "vital policy considerations" underlying the privacy to which even summary personal financial information about an individual is entitled. *Id.* at 121. Thus, plaintiffs' argument is completely undercut by the Third Circuit's DeMasi decision.

Plaintiffs contend that the existence of the Stipulation and Protective Order (the "Protective Order") (July 26, 2004) in this litigation suffices to protect *amici's* privacy interests. Mot. to Intervene Opp. at 5 n.2, 13 n.5, 14. That argument completely misses the mark. The question for the Court is whether the JAMA Authors' privacy interests are implicated by the disclosure of their compensation records to plaintiffs. To be sure, the Protective Order may for a time help keep sensitive documents and information out of the hands of non-parties to the litigation, but *amici's* privacy interests include preventing their personal financial information from coming into the hands of the plaintiffs in this case.³

³ It is important to note that the confidentiality order in this case does not allow documents to be designated as "Highly Confidential" or "For Attorneys' Eyes Only." Stipulation and Protective Order at ¶¶ 3-4 (July 26, 2004). Under the

Moreover, plaintiffs' reliance on the protective order is disingenuous in light of plaintiffs' motion to modify the protective order to make more than 400,000 pages of documents produced in discovery available to the public.⁴

Finally, plaintiffs have argued that the fact that the personal financial information is being sought from defendants and not directly from *amici* is a factor that weighs against the relief *amici* seek (Mot. to Intervene Opp. at 4-5). This argument is of no moment, for it is the information itself -- and not its source -- that gives rise to the privacy right advanced by *amici*.

C. The Relevance Of The Requested Information Is Marginal

In their consolidated complaint, plaintiffs have alleged violations of the federal securities laws by defendants through the publication and dissemination of the JAMA Article, which reported the results of the CLASS Study. Consolidated

existing order, notwithstanding a document's designation by a party as "Confidential," it may be reviewed by numerous representatives of each party, by "any individual or entity that, in the good faith belief of counsel, is aware of the information," and by "any outside consultant or expert who is assisting a party to the Action . . . regardless of whether the expert is formally retained by the party itself." *Id.* at ¶ 8. Even assuming that plaintiffs are entitled to this information, *amici* certainly would be entitled to stricter prohibitions on dissemination of their highly personal financial data than currently provided for in the confidentiality order.

⁴ Plaintiffs' motion to modify the protective order strongly suggests that plaintiffs similarly would have no interest in assuring the confidentiality of *amici*'s personal financial information. To the contrary, as with the documents plaintiffs seek to de-designate as Confidential, plaintiffs' interest is in using *amici*'s highly personal information to their perceived strategic advantage in the case.

Complaint (“Complaint”) ¶¶ 4, 5, 76, 77. There is no suggestion in the Complaint that any other research conducted by *amici* violated the law or otherwise caused injury or damage to plaintiffs. The only allegations in the Complaint involving *amici* center on whether they properly reported the results of the CLASS Study in the JAMA Article. Thus, the relevance of documents disclosing all sums paid to *amici* for work not related to the CLASS Study and the publication of the JAMA Article is tangential at best.

In offering to provide plaintiffs with records of their compensation related to the conduct of the CLASS Study and the publication of the JAMA Article, *amici* have struck a fair and reasonable balance between the plaintiffs’ ability to establish *amici*’s alleged bias⁵ and the *amici*’s own well-recognized right to privacy. Plaintiffs, however, are not satisfied with the compromise offered by *amici*. Rather, plaintiffs seek to intrude further on *amici*’s privacy rights in order to demonstrate what plaintiffs have called a “greater amount of bias.” Mot. to Intervene Opp. at 12 (emphasis omitted). This is where the Court should draw the line, for whatever marginal benefit plaintiffs might obtain from the disputed

⁵ In Hecht v. Pro-Football, Inc., 46 F.R.D. 605, 607 (D.D.C. 1969), the Court noted that even if evidence sought in a subpoena *duces tecum* may be relevant at the time of trial, “it seems oppressive and unreasonable to disclose [non-party financial records] in advance when many things may happen between now and the trial that may make the disclosure unnecessary.” This strongly suggests that whatever relevance the information sought in this case may have, disclosure at this early date is premature.

information does not outweigh the significant additional intrusion on *amici's* privacy rights. Indeed, the probative value of the additional information sought by plaintiffs is so attenuated that it is greatly outweighed by the injury *amici* would suffer. See 8 Charles A. Wright and Arthur R. Miller, *Federal Practice and Procedure*, §2015 at 209-210 (1994) (“[o]pening the door to untrammelled discovery regarding any topic that might be used for impeachment strains the outer limits of discovery ‘reasonably calculated to lead to the discovery of admissible evidence’”).

Amici's proposed compromise solution will enable plaintiffs to cross-examine *amici* about their financial incentives, if any, in conducting the CLASS Study and publishing the JAMA Article, while avoiding the potential development of “side trials” regarding payments made to *amici* for other projects. This precise issue was raised in the context of expert witness discovery in Behler v. Hanlon, 199 F.R.D. 553 (D. Md. 2001). In Behler, the district court considered a motion to compel a defense expert witness to provide wide-ranging information over a five year period. Id. at 561. The district court found the requested information to be “overkill,” especially without a showing why less intrusive information would not suffice. Id. In limiting the discovery that the plaintiff could obtain from the expert witness, the court recognized “the real possibility of confusion, distraction and even prejudice” that would result by introducing such evidence at trial, either by

the proponent of the witness in attempting to take the “sting” out of the information or the opponent in attempting to impugn credibility. Id. at 562. See also Wacker v. Gehl Co., 157 F.R.D. 58, 59 (W.D. Mo. 1994) (“[g]eneral information as to past earnings of an expert would, as plaintiff has suggested, open up numerous collateral issues, resulting in delay and confusion at trial”). Allowing discovery of collateral matters such as compensation received for other consulting projects will lead to this same confusion, distraction and prejudice.⁶

In an analogous context, the United States District Court for the Southern District of New York addressed the scope of permissible discovery concerning witness compensation. In Cary Oil Co. v. MG Refining & Marketing, Inc., 257 F. Supp. 2d 751 (S.D.N.Y. 2003), the plaintiffs sought to compel production by the defendants of all communications concerning retention and payment to two expert witnesses who had written reports for the defendant in connection with the subject litigation and in an earlier proceeding. Id. at 756. The plaintiffs’ stated purpose in pursuing the information through discovery was to show that the witnesses had

⁶ For example, certain of the *amici* have consulting arrangements with one of the defendants to provide scientific support for the development of a new cancer drug. In that instance, the particular scientist was paid for the entire project, but subcontracted certain scientific, data management and support tasks to others. If information concerning payments to the *amicus* were produced to plaintiffs, it would not accurately reflect the net sums received by the particular *amicus* for his work and would require additional testimony to explain the details and finances of a research project wholly unrelated to the claims here. The Court can and should limit inquiry into such collateral matters.

financial incentives to change their opinions over time to satisfy the defendants' evidentiary needs in the different cases. *Id.* While the court acknowledged the right of a party to explore bias on cross-examination, it balanced that right against the risk of harassing litigants and their expert witnesses under the guise of seeking impeachment evidence. *Id.* at 757. As a result, the court found that such an inquiry "both at the discovery and trial stages, should be tightly controlled by the trial court and limited to its purpose." *Id.* (internal quotation omitted). Applying this principle, the court required the plaintiffs to demonstrate a factual basis to suggest that an expert witnesses' receipt of compensation affected the expert's opinion. *Id.* In contrast, plaintiffs in the instant case have alleged no factual basis to suggest that *amici's* compensation unrelated to the conduct of the CLASS Study and the publication of the JAMA Article affected their scientific opinions in connection with the conduct of the CLASS Study and the publication of the JAMA Article.

D. Important Public Policy Interests Outweigh the Plaintiffs' Interest in Obtaining *Amici's* Financial Information

In deciding whether to grant plaintiffs broad access to *amici's* personal financial information, the Court also should consider the strong public policy reasons counseling against disclosure. Other courts have concluded that the need to encourage medical research provides a compelling reason to protect from

discovery information related to clinical trials. While those cases did not involve the precise type of information sought here, they nonetheless are instructive.

In Harris v. Upjohn Co., 115 F.R.D. 191 (S.D. Ill. 1987), plaintiffs sought the names of non-party physicians who submitted adverse drug reaction reports to a company conducting a drug study. The court refused to order the disclosure of the non-party physicians' names on public policy grounds, holding that "[t]he potential of future disclosure of the names of treating physicians who communicate with researchers would deter some physicians who fear such disclosures would bring about inquiries from attorneys. Unfounded or not, this fear is a deterrent on efforts to conduct research in the medical and science community." Harris, 115 F.R.D. at 192.

The facts in Farnsworth v. Procter & Gamble Co., 758 F.2d 1545 (11th Cir. 1985), also are analogous to the instant case. There, Procter & Gamble appealed the entry of a protective order forbidding disclosure of the names and addresses of patients participating in a Toxic Shock Syndrome study conducted at the Center for Disease Control. Much like the plaintiffs in the present action, Procter & Gamble "hoped to discredit the Center study by pointing out certain purported 'biases' in the methodology." Id. at 1546.

The Eleventh Circuit acknowledged that the defendant had an interest in obtaining the names and addresses of the study participants, but also recognized

the district court's duty to "balance P & G's interest . . . against the Center's interest in keeping that information confidential" and against the "highly personal nature" of the information sought. *Id.* at 1546-1547. The court found that the patients at issue had a justifiable expectation that their personal information would remain private. *Id.* at 1547. As a result, the court upheld the district court's order preventing disclosure of such information because it would deter participation in the study.

Here, *amici* have demonstrated that broad disclosure of private financial information would have a chilling effect on the participation of experts in future clinical research studies. *Amicus* Dr. Lee Simon, a board-certified rheumatologist and Associate Clinical Professor of Medicine at Harvard Medical School who served on the executive committee of the CLASS study and co-authored the JAMA Article, has averred that if plaintiffs are permitted access to information about his remuneration on matters unrelated to the conduct of the CLASS Study and publication of the JAMA Article, he "would likely decline to participate as an investigator in future research or clinical trials sponsored by pharmaceutical companies or others in the field of medicine who may become involved in litigation." Declaration of Lee S. Simon, M.D. in Support of Motion to Intervene at ¶ 7 (Exhibit 1 to Motion for Leave to Intervene). Plaintiffs attempt to dismiss Dr. Simon's legitimate concerns as "nonsense," Mot. to Intervene Opp. at 14, but

the potential chilling effect is real and Dr. Simon's Declaration on this issue stands un rebutted in the record.

* * *

In sum, *amici's* reasonable expectations of privacy and strong public policy considerations counsel in favor of denying plaintiffs access to personal financial information beyond that associated with *amici's* participation in the conduct of the CLASS study and in the publication of the JAMA Article.

CONCLUSION

For the reasons set forth above, the Court should grant the protective order sought by defendants to prevent disclosure of *amici's* personal financial information beyond that associated with their participation in the conduct of the CLASS Study and in the publication of the JAMA Article.

REQUEST FOR LEAVE TO PARTICIPATE IN ORAL ARGUMENT

Amici respectfully request leave to participate in oral argument in support of defendants' motion for a protective order and in opposition to plaintiffs' motion to compel.

Respectfully submitted,

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